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January 5, 2024

BY ECF

Hon. Julien Xavier Neals, U.S.D.J.
United States District Court for the District of New Jersey
Martin Luther King Jr. Bldg. & U.S. Courthouse
50 Walnut Street
Newark, New Jersey 07102

BY ECF & EMAIL

Hon. Faith S. Hochberg, U.S.D.J. (Ret.)
Special Master
80 United Nations Plaza, Suite 12F
New York, NY 10017

Re: ***Mylan Pharms. Inc. v. Teva Pharms. Indus. Ltd., et al.*,**
Civil Action No. 2:21-13087 (JXN) (JSA)

Dear Judge Neals and Judge Hochberg:

Our firm, along with Wilson Sonsini Goodrich & Rosati, represents Plaintiff Mylan Pharmaceuticals Inc. in this matter. We write in response to Teva's December 29, 2023 letter to the Court regarding the relevance of *Azurity Pharms., Inc. v. Bionpharma Inc.*, 650 F. Supp. 3d 269 (D. Del. 2023) ("Exhibit A"), which Mylan cited at the December 12 hearing on Teva's motion to dismiss.

Teva erroneously contends that "*Azurity* does not support allowing Mylan's case to go forward in any respect." Quite to the contrary, *Azurity* squarely supports Mylan's positions not just for those topics discussed during oral argument (the applicability of the objective baselessness standard to serial petitioning in the Hatch-Waxman context, and ANDA approval triggering accrual for statute of limitations purposes) but for several other issues as well, including the non-applicability of *Noerr-Pennington* immunity at the motion to dismiss stage ("[A]lthough it is sometimes possible to decide whether a lawsuit was objectively baseless 'as a matter of law,' . . . at the pleadings stage," that is not true where "not all of the facts underlying [the plaintiff]'s antitrust allegations are undisputed."), i*d*. at 280, and the deference afforded to a generic manufacturer's causation allegations vis-à-vis FDA approval at the motion to dismiss stage ("[Plaintiff's] allegation that the 30-month stay delayed its entry must be accepted as true

at the pleadings stage . . . [Defendant's] counterargument implicates a factual dispute that is not appropriate for resolution at this stage of the litigation."). *Id*. at 279.

Indeed, Judge Goldberg's[1] decision provides a roadmap for evaluating the very issues advanced by Teva in its motion to dismiss, whether taken discretely, or considered in the aggregate as part of the overarching monopolization scheme alleged in Mylan's complaint. Whichever approach, the guidance from Judge Goldberg in *Azurity* is the same: dismissal is inappropriate.

Mylan did not cite the *Azurity* decision in its brief because the opinion was issued in January 2023, nine months after briefing on Teva's motion completed. Mylan raised this case in direct response to questions posed by the Court during the December 12 hearing (Hr'g Tr. at 56:17-22 & 63:7-10 (serial petitioning and Hatch-Waxman); *id.* at 76:16-22 & 77:8-20 (accrual date of sham litigation claim)), and the Court afforded Teva the opportunity to respond (*id.* at 66:10-15), which it has now done in three pages of letter-briefing.

Teva's additional arguments are similarly unavailing:

First, Teva's point that *Azurity* discussed claim accrual in the context of whether an antitrust claim predicated on sham litigation is a compulsory counterclaim in the sham suit, not in the context of a statute of limitations defense, is not legally relevant. A claim either accrues or it does not, whatever the purpose of evaluating this accrual. Moreover, Teva's own primary authority on claim accrual, *Perrigo v. AbbVie*, is not a statute of limitations case either, as it deals with claim accrual in the context of a release from liability.[2]

In analyzing the compulsory counterclaim issue, the *Azurity* court "recognized the possibility that antitrust claims might not accrue until sometime after Hatch-Waxman infringement litigation plays out." *Azurity*, 650 F. Supp. 3d at 277. As the court explained: when, at the time sham patent infringement suits are filed "there [is] no guarantee that the FDA [will]

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[1] Judge Goldberg sits by designation in the District of Delaware from the Eastern District of Pennsylvania pursuant to 28 U.S.C. § 292(b) for this and other District of Delaware cases.

[2] *Perrigo*, for its part, actually supports Mylan's position. Like *Azurity*, both the district court and court of appeals in *Perrigo* recognized that the *Zenith* speculative damages rule can delay accrual of an antitrust claim until an ANDA applicant receives tentative or final approval. *See Perrigo Co. v. AbbVie Inc.*, 2022 WL 2870152, at *5 & n.12 (3d Cir. July 21, 2022) (acknowledging the *Zenith* rule would postpone accrual had the plaintiff shown "it was uncertain *whether* they would suffer damages" but, unlike Mylan, the plaintiff had only alleged uncertainty as to "*when* the FDA would approve the [] generic").

ever approve [the] ANDA[s]," it is "unknown at [that] time whether the [patent] lawsuits [will] ever suppress competition, even if they were brought in bad faith." *Id.*

Second, Teva's assertion that *Azurity*'s causation analysis does not support Mylan's case is incorrect. Mylan did not cite *Azurity* for a causation argument at the hearing, but in any event the decision does support Mylan's case. *Azurity* held that there is no fatal causation defect to a generic manufacturer's antitrust claim when the relevant Hatch-Waxman 30-month stay expired before the generic applicant received final approval from the FDA because the plaintiff's allegations of delay must be taken as true at the pleading stage. 650 F. Supp. 3d at 279. Any counterargument necessarily "implicates a factual dispute that is not appropriate for resolution at this stage of the litigation." *Id*. Teva's focus on the length of the gap ("FDA approval promptly after it won the patent litigation (just 3.5 months later) . . . yet the FDA did not grant approval of Mylan's 40 mg GA for another eight months") underscores that this is a question of fact. Moreover, Teva overlooks the wealth of caselaw in the Third Circuit reiterating the principle that whether a 30-month stay delays an ANDA applicant's entry—even when that stay expires before the applicant receives final approval—is a question of fact. *See, e.g.*, *Takeda Pharm. Co. v. Zydus Pharms. (USA) Inc.*, 358 F. Supp. 3d 389, 398-99 (D.N.J. 2018) (collecting cases).

Third, Teva's claim that *Azurity* does not support Mylan's arguments as to when multiple lawsuits constitute a "series"—an important step in the process for deciding which test to apply for determining whether lawsuits are shams—is incorrect.[3] In its briefs, Teva asserted that Third Circuit precedent (*In re Wellbutrin XL Antitrust Litig.*, 868 F.3d 132 (3d Cir. 2017)) prohibits application of the serial petitioning rule in the Hatch-Waxman context. *Azurity* squarely rejected this argument and explains how Teva misapplies *Wellbutrin*.

As *Azurity* makes clear, and as we explained at oral argument, *Wellbutrin* only prohibits application of the serial test where the brand filed Hatch-Waxman cases against *multiple generics* and not where the brand serially files Hatch-Waxman litigation against the *same generic*. *Azurity* confirms the serial rule applies in the latter scenario, including in the case at bar. 650 F. Supp. 3d at 281-82.

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[3] As the Court will recall, there are two different tests for identifying when a lawsuit is a sham and therefore devoid of *Noerr-Pennington* immunity—one test for *single* petitions and a second test for a *series* of petitions. *See Hanover 3201 Realty, LLC v. Vill. Supermarkets, Inc.*, 806 F.3d 162, 179-80 (3d Cir. 2015). Teva's parade of filings—encompassing eight citizen petitions, two Hatch-Waxman lawsuits, two additional patent suits against Mylan, patent suits against Mylan's foreign suppliers, and two suits against the FDA—constitute a series. At issue here is whether the "more flexible" test for a series can be applied to those sham petitions that are Hatch-Waxman cases. *Id.* at 180.

Fourth, Teva fixates on the fact that in *Azurity* the alleged antitrust injury was litigation costs incurred in defending allegedly sham lawsuits and then argues that *Azurity*'s discussion of this antitrust injury is irrelevant to Mylan's case because Mylan does not allege any antitrust injury owing to litigation costs in any lawsuit filed by Teva against Mylan. As with Teva's other arguments, this is nothing more than an ineffectual attempt to distinguish *Azurity* by latching onto an immaterial difference between that case and this one and pretending it is material. Mylan primarily alleges antitrust injury in the form of exclusion from the market while Teva delayed Mylan's approval and diminished its uptake.[4] That *Azurity* recognized litigation costs as a valid antitrust injury says nothing about whether Mylan's different antitrust injury is viable. And Teva's suggestion otherwise is a non sequitur given that Mylan did not cite *Azurity* for its antitrust injury holding.

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We thank the Court for its consideration of this matter. Naturally, if the Court has any questions, we are available to respond at the Court's convenience.

Respectfully submitted,

/s *Jakob B. Halpern*

Jakob B. Halpern

/jbh

cc: Counsel of Record (by ECF)

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[4] As Teva acknowledges in its letter (at 4 n.1), Mylan's complaint does allege injury in the form of litigation expenses in connection with Teva's sham litigation. And Mylan's Prayer for Relief seeks "[d]amages in an amount to be proven at trial" and all "further and other relief as the Court deems just and proper." Compl. at 86. Accordingly, Mylan has not excluded the possibility of seeking damages tied to the cost of litigating Teva's sham lawsuits.

In attempting to avoid liability for these litigation costs, Teva relies in its letter on *Otsuka Pharm. Co. v. Torrent Pharms. Ltd., Inc.*, 187 F. Supp. 3d 483 (D.N.J. 2016). But that case is fully compatible with Mylan's claim. Mylan bore the cost of opposing Teva's sham lawsuits against the FDA that, if successful, would not only have injured Mylan individually but would have excluded all generic competitors, upending the "competitive landscape" and injuring "the market-at-large." *Id.* at 487. That is textbook antitrust injury.

EXHIBIT A

nificantly lower costs to the Plan for the exact same investments"). Instead, the plaintiffs allege only that the funds offered to them by the 401(k) Plan were more expensive than other funds. Without pleading facts indicating additional indicia of imprudence, the plaintiffs have not alleged plausibly that the plan fiduciaries breached their duty of prudence. Accordingly, the defendants' motion to dismiss the claim of fiduciary breach is **granted.**

IV.

The plaintiffs also bring a claim for a failure to monitor. Both parties agree that this claim is derivative of the plaintiffs' claim of a breach of fiduciary duty. Because the plaintiffs have insufficiently pleaded their claim for a breach of fiduciary duty, the defendants' motion to dismiss the derivative claim for failure to monitor is likewise **granted.** See Coulter v. Morgan Stanley & Co., 753 F.3d 361, 368 (2d Cir. 2014) (finding that failure to monitor claims "cannot survive absent a viable claim for breach of a duty of prudence").

CONCLUSION

The Court has considered all of the arguments of the parties. To the extent not specifically addressed above, the arguments are either moot or without merit. For the foregoing reasons, the defendant's motion to dismiss is **granted.** The complaint is dismissed without prejudice to the ability of the plaintiffs to move to file an amended complaint. Any such motion must be filed within thirty days of the date of this Memorandum Opinion and Order and explain how any proposed amended complaint would resolve the defects in the current complaint.

SO ORDERED.

AZURITY PHARMACEUTICALS, INC., Plaintiff,

v.

BIONPHARMA INC., Defendant.

Civil Action Nos. 21-cv-1286, 21-cv-1455

United States District Court,
D. Delaware.

Filed January 11, 2023

Background: Drug maker that held patents on, and sold branded version of, a liquid formulation of enalapril, a blood-pressure medication, brought infringement action against generic competitor that had filed an abbreviated new drug application (ANDA) with the Food and Drug Administration (FDA) for a formulation of enalapril. Competitor brought sham-litigation counterclaims under the Sherman Act, alleging that drug maker's suit and a series of similar prior suits were brought in bad faith to stifle competition. Drug maker moved to dismiss competitor's antitrust counterclaims for failure to state a claim.

Holdings: The District Court, Mitchell S. Goldberg, visiting District Judge, held that:

(1) competitor's antitrust counterclaims were not compulsory counterclaims in prior infringement actions between drug maker and competitor;

(2) competitor's litigation costs in defending prior infringement suits constituted an antitrust injury;

(3) competitor's allegation that prior infringement suits delayed its entry into the market by 30 months because of the automatic Hatch-Waxman Act stay was sufficient to allege the causation element of competitor's antitrust counterclaims;

(4) competitor sufficiently alleged, for purposes of defeating patentee's assertion

at the pleading stage of *Noerr-Pennington* immunity from antitrust liability arising from its lawsuits, that patentee's lawsuits were objectively baseless; and

(5) competitor sufficiently alleged, for purposes of defeating patentee's assertion at the pleading stage of *Noerr-Pennington* immunity from antitrust liability arising from its lawsuits, that patentee's lawsuits were subjectively brought in bad faith, with the intent of suppressing competition.

Motion denied.

1. Federal Civil Procedure ⚿1772, 1835

To determine the sufficiency of a complaint on a motion to dismiss for failure to state a claim, a court must (1) take note of the elements a plaintiff must plead to state a claim; (2) identify the allegations that are not entitled to the assumption of truth because they are no more than conclusions; and (3) where there are well-pleaded factual allegations, assume their veracity and then determine whether they plausibly give rise to an entitlement for relief. Fed. R. Civ. P. 12(b)(6).

2. Federal Civil Procedure ⚿1832

When deciding a motion to dismiss, courts generally consider only the allegations contained in the complaint, exhibits attached to the complaint, and matters of public record. Fed. R. Civ. P. 12.

3. Federal Civil Procedure ⚿776

A counterclaim is compulsory if it bears a logical relationship to the primary claim; a logical relationship, in turn, depends on whether the two claims involve many of the same factual issues, or the same factual and legal issues, or where they are offshoots of the same basic controversy between the parties.

4. Federal Civil Procedure ⚿777

Malicious-prosecution claims are generally not considered compulsory counterclaims.

5. Antitrust and Trade Regulation ⚿983

Future antitrust damages that might arise from the conduct sued on are unrecoverable if the fact of their accrual is speculative or their amount and nature unprovable; in these instances, the cause of action for future damages, if they ever occur, will accrue only on the date they are suffered.

6. Patents ⚿1791

Antitrust counterclaims brought by defendant, a generic drug maker, in infringement suit by patentee, a competing branded drug maker with patents on a liquid formulation of enalapril, a blood-pressure medication, alleging that patentee's suit and prior suits were brought in bad faith to stifle competition were not compulsory counterclaims in prior infringement suits between patentee and defendant, and defendant's failure to bring its antitrust counterclaims in those prior suits thus was not a basis for dismissing those counterclaims, where at the time of those suits there was no guarantee defendant's generic drug would be approved by the Food and Drug Administration (FDA) or that defendant would suffer an antitrust injury. Sherman Act § 2, 15 U.S.C.A. § 2; Clayton Act §§ 4, 16, 15 U.S.C.A. §§ 15, 26.

7. Antitrust and Trade Regulation ⚿963(3)

Litigation costs incurred by defendant, a generic drug maker, in defending prior infringement suits by patentee, a competing branded drug maker with patents on a liquid formulation of enalapril, a blood-pressure medication, constituted an antitrust injury for purposes of defendant's antitrust counterclaims, in later

infringement suit by patentee against defendant, asserting that patentee's infringement suits were brought in bad faith to suppress competition, even though patentee had lost in prior suits and had failed to keep generic drug maker's product off the market. Sherman Act § 2, 15 U.S.C.A. § 2; Clayton Act §§ 4, 16, 15 U.S.C.A. §§ 15, 26.

8. Antitrust and Trade Regulation ⚿905(3)

Allegation by defendant, a generic drug maker, that prior infringement suits against it by patentee, a competing branded drug maker with patents on a liquid formulation of enalapril, a blood-pressure medication, delayed defendant's entry into the market by 30 months because of the automatic stay that applied in Hatch-Waxman Act litigation was sufficient, in subsequent infringement action by patentee against defendant, to allege the causation element of defendant's antitrust counterclaims asserting that patentee's prior suits amounted to sham litigation intended to suppress competition. Sherman Act § 2, 15 U.S.C.A. § 2; Clayton Act §§ 4, 16, 15 U.S.C.A. §§ 15, 26.

9. Antitrust and Trade Regulation ⚿905(3)

Constitutional Law ⚿1437(2)

To overcome *Noerr-Pennington* immunity, an antitrust plaintiff whose claim is based on a lawsuit that was allegedly brought for anticompetitive purposes must show that: (1) the lawsuit was objectively baseless in the sense that no reasonable litigant could have realistically expected success on the merits; and (2) the baseless lawsuit conceals an attempt to interfere directly with the business relationships of a competitor through the use of the governmental process—as opposed to the outcome of that process—as an anticompetitive weapon. U.S. Const. Amend. 1.

10. Antitrust and Trade Regulation ⚿905(3)

Constitutional Law ⚿1437(2)

Defendant, a generic drug maker, sufficiently alleged that patentee, a competing branded drug maker with patents on a liquid formulation of enalapril, a blood-pressure medication, had no basis to believe it could prevail in patentee's prior infringement suits, and that the suits were thus objectively baseless, and defendant's allegations supporting its antitrust counterclaims against patentee asserting that the prior suits were anticompetitive sham litigation were thus sufficient at the pleading stage to satisfy the objective-baselessness element required for defendant to defeat patentee's assertion of *Noerr-Pennington* immunity as a basis to dismiss the counterclaims, where defendant alleged that patentee knew that it could not overcome prosecution-history estoppel and an invalidity defense. U.S. Const. Amend. 1; Sherman Act § 2, 15 U.S.C.A. § 2; Clayton Act §§ 4, 16, 15 U.S.C.A. §§ 15, 26.

11. Antitrust and Trade Regulation ⚿905(3)

Constitutional Law ⚿1437(2)

Defendant, a generic drug maker, sufficiently alleged that patentee, a competing branded drug maker with patents on a liquid formulation of enalapril, a blood-pressure medication, brought prior infringement suits against defendant in bad faith, to suppress competition, and defendant's allegations supporting its antitrust counterclaims against patentee asserting that the prior suits were anticompetitive sham litigation were thus sufficient at the pleading stage to satisfy the subjective-motivation element required for defendant to defeat patentee's assertion of *Noerr-Pennington* immunity as a basis to dismiss the counterclaims, where defendant alleged that before bringing suit, patentee turned down information relevant to the merits, and patentee had brought seven

lawsuits in three courts. U.S. Const. Amend. 1; Sherman Act § 2, 15 U.S.C.A. § 2; Clayton Act §§ 4, 16, 15 U.S.C.A. §§ 15, 26.

12. Antitrust and Trade Regulation ⚿905(3)

Constitutional Law ⚿1437(2)

Under the subjective-motivation prong for overcoming *Noerr-Pennington* immunity, an antitrust plaintiff whose claim is based on a lawsuit that was allegedly brought for anticompetitive purposes must show the defendant brought baseless claims in an attempt to thwart competition (i.e., in bad faith). U.S. Const. Amend. 1.

Patents ⚿2091

9,669,008, 9,808,442, 10,039,745, 10,154,987, 10,772,868, 10,786,482, 10,918,621, 11,040,023, 11,141,405. Cited.

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MEMORANDUM OPINION

Goldberg, District Judge [1]

These cases comprise what the parties refer to as the "Third Wave" in an ongoing patent infringement dispute between Plaintiff Azurity Pharmaceuticals, Inc. ("Azurity") and Defendant Bionpharma Inc. ("Bionpharma"). The parties' dispute revolves around Bionpharma's generic enalapril oral liquid. Bionpharma's counterclaims assert antitrust "sham litigation" claims under the Sherman Act, 15 U.S.C. §§ 2, 15, and 26, alleging that Azurity brought these and other lawsuits in bad faith to stifle competition. Bionpharma claims that these lawsuits were objectively baseless and brought only to force Bionpharma to incur litigation costs and delay market entry for the duration of the 30-month stay applicable to Hatch-Waxman litigation.

Before me is Azurity's motion to dismiss the antitrust counterclaims. For the reasons that follow, Azurity's motion will be denied.

I. FACTUAL AND PROCEDURAL BACKGROUND

The following facts are taken from Bionpharma's Answer and Counterclaims, and, where appropriate, matters of public record regrading the litigation history between Azurity and Bionpharma. These facts will be viewed in the light most favorable to Bionpharma. See Burtch v. Milberg Factors, Inc., 662 F.3d 212, 221 (3d Cir. 2011).

A. Azurity's EPANED Product and Related Patents

Azurity's brand product EPANED is an oral liquid formulation of the blood pressure medicine enalapril. (Answer [2] ¶ 9;

1. Pursuant to 28 U.S.C. § 292(b), I have been designated to serve as a visiting judge for the District of Delaware to handle this matter and other District of Delaware cases.

2. Paragraph citations to "Answer" refer to Docket Entry 26 in 21-cv-1455. Paragraph citations to "Counterclaims" refer to paragraphs beginning on page 10 of that document.

Counterclaims ¶¶ 13, 34-35.) EPANED "is the only ready-to-use oral solution of enalapril, which caters to specific populations of patients that have trouble swallowing solid oral dosage forms." (Counterclaims ¶ 38.)

From March 2016 to April 2021, Azurity filed nine patent applications for enalapril liquids, each a continuation of a prior application, and each with a priority date of March 18, 2016.[3] The precise claim limitations differ from patent to patent, but the essence of each is a stable mixture of water, enalapril, and other ingredients such as buffers, preservatives, and sweeteners. The following claims from two of those patents are illustrative:

> A stable oral liquid formulation, comprising:
>
> (i) about 1 mg/ml enalapril maleate;
>
> (ii) a buffer comprising about 1.82 mg/ml citric acid and about 0.15 mg/mL sodium citrate dihydrate;
>
> (iii) about 1 mg/ml of a preservative that is sodium benzoate; and
>
> (iv) water;
>
> wherein the pH of the formulation is less than about 3.5; . . .
>
> wherein the formulation is stable at about 5 ± 3° C. for at least 12 months; [and]
>
> wherein the stable oral liquid formulation has about 95% or greater of the initial enalapril amount and about 5% w/w or less total impurities or related substances at the end of the given storage period.

(Claim 1 of the '008 patent.)

> A stable oral liquid formulation, comprising:
>
> (i) about 0.6 to about 1.2 mg/ml enalapril or a pharmaceutically acceptable salt or solvate thereof;
>
> (ii) a buffer comprising about 0.8 to about 3.5 mg/ml citric acid and about 0.1 to about 0.8 mg/ml sodium citrate;
>
> (iii) about 0.7 to about 1.2 mg/ml sodium benzoate; and
>
> (iv) water;
>
> wherein the formulation is stable at about 5 ± 3° C. for at least 12 months; and
>
> wherein the stable oral liquid formulation has about 95% w/w or greater of the initial enalapril amount and about 5% w/w or less total impurity or related substances at the end of the given storage period.

(Claim 1 of the '745 patent.)

B. Bionpharma's ANDA

In August 2018, Bionpharma filed an abbreviated new drug application (ANDA) with the Food and Drug Administration (FDA) for a generic oral enalapril liquid. (Counterclaims ¶¶ 14, 63.) Bionpharma alleges that its ANDA differs from Azurity's EPANED product in that it does not contain a buffer and uses a preservative consisting of parabens rather than sodium benzoate. (Counterclaims ¶ 61.) Bionpharma alleges it made these alterations to "design . . . around" Azurity's patents. (Id.)

To date, Azurity has filed seven lawsuits in three separate courts regarding Bionpharma's generic enalapril liquid—five against Bionpharma and two against Bionpharma's contract manufacturer, CoreRx.[4]

3. These applications issued as U.S. Patent Nos. 9,669,008 (the '008 patent), 11,040,023 (the '023 patent), 11,141,405 (the '405 patent), 9,808,442 (the '442 patent), 10,786,482 (the '482 patent), 10,918,621 (the '621 patent), 10,039,745 (the '745 patent), 10,772,868 (the '868 patent), and 10,154,987 (the '987 patent).

4. For reference, Azurity's seven lawsuits over Bionpharma's ANDA are summarized in the table below:

C. Bionpharma's Paragraph IV Notice to Azurity

When a generic manufacturer files an ANDA, it must send a notice (a "Paragraph IV Notice") to patentholders listed for the brand drug in the FDA's "Orange Book." See 21 U.S.C. § 355(j)(2)(B). In October 2018, Bionpharma sent a Paragraph IV Notice to Azurity regarding the '008, '442, and '745 patents. (Counterclaims ¶ 64.)

Bionpharma's Paragraph IV Notice offered to provide Azurity with confidential access to Bionpharma's ANDA, under terms similar to those used in prior litigation between Azurity and Bionpharma. (Counterclaims ¶ 65.) Bionpharma requested that Azurity agree not to share information with its patent prosecution counsel (an agreement called a "patent prosecution bar") because Azurity had patent prosecution open for enalapril liquids and Bionpharma was concerned that Azurity could file new applications targeted to Bionpharma's ANDA. (Counterclaims ¶ 68.) Azurity declined the offer of confidential access, and Bionpharma alleges that Azurity did so because Azurity was indifferent to the merits of its infringement position. (Counterclaims ¶¶ 65, 70-71.)

D. Azurity's Lawsuits Against Bionpharma

From December 12, 2018 to October 15, 2021, Azurity filed five lawsuits against Bionpharma only over Bionpharma's generic enalapril liquid. Collectively, these lawsuits involve all nine of Azurity's patents for enalapril liquids. The parties refer to groups of these lawsuits as the "First Wave," "Second Wave," and "Third Wave."

The First Wave (Nos. 18-cv-1962 and 19-cv-1067) involved the '008, '442, '745, and '987 patents. In February 2021, the Honorable Leonard Stark held a bench trial on these patents and on April 27, 2021 entered judgment for Bionpharma, finding that:

(1) Prosecution history estoppel precluded Azurity from claiming that the active ingredient in Bionpharma's ANDA, enalapril maleate, was equivalent to the citrate buffer limitation in the asserted claims;

(2) Azurity failed to prove that enalapril maleate acted as a buffer; and

(3) Azurity could not claim parabens as equivalent to the claimed preservative sodium benzoate because parabens were disclosed in the specification but not claimed.

(See No. 19-1067, Docket Entry 244.) The Court of Appeals for the Federal Circuit affirmed Judge Stark's findings without an opinion. See Azurity Pharmaceuticals, Inc. v. Bionpharma Inc., No. 2021-1926, 2022 WL 703903 (Fed. Cir. March 9, 2022).

The Second Wave lawsuit (No. 20-cv-1256) involved the '868, '482, and '621 patents. After the Federal Circuit's affirmance became final in the First Wave suits, Azurity stipulated to dismissal of the Second Wave lawsuit.

Docket No.	Defendant	Filed In	Filed On	Patents
D. Del. 18-1962	Bionpharma	D. Del.	12/12/2018	'008, '442, '745
D. Del. 19-1067	Bionpharma	D. Del.	6/7/2019	'987
D. Del. 20-1256	Bionpharma	D. Del.	9/18/2020	'868, '482, '621
D. Del. 21-1286	Bionpharma	D.N.J.	6/22/2021	'023
D. Del. 21-1455	Bionpharma	D. Del.	10/15/2021	'405
M.D. Fla. 21-2515	CoreRx	M.D. Fla.	10/26/2021	'023, '405
D. Del. 21-1522	CoreRx	D. Del.	10/27/2021	'023, '405

The Third Wave lawsuits (Nos. 21-cv-1286 and 21-cv-1455), which are ongoing, involve the '023 and '405 patents. One of these lawsuits (No. 21-cv-1286) was originally filed in the District of New Jersey and transferred to this Court on Bionpharma's motion.

All of these lawsuits were reassigned to me on March 2, 2022.

E. Azurity's Acquisition of and Lawsuits Against CoreRx

Bionpharma contracted with a third party, CoreRx, Inc. ("CoreRx") to develop and manufacturer the enalapril oral liquid that became Bionpharma's ANDA. (Counterclaims ¶ 13.) In January 2021, Azurity's corporate parent, NovaQuest Capital Management ("NovaQuest") acquired a controlling interest in CoreRx. (Counterclaims ¶ 17.) As of February 2022, Azurity and CoreRx had several directors in common on their respective corporate boards. (Counterclaims ¶¶ 19-22.)

After NovaQuest acquired CoreRx, Azurity sued its new corporate sister twice, in two different courts, for infringing Azurity's patents by manufacturing Bionpharma's ANDA. See Azurity Pharmaceuticals, Inc. v. CoreRx, Inc., No. 21-cv-2515 (M.D. Fla. filed October 26, 2021); Azurity Pharmaceuticals, Inc. v. CoreRx, Inc., No. 21-cv-1522 (D. Del. filed October 27, 2021). Bionpharma alleges that Azurity and CoreRx were not genuinely adverse parties in these law-suits because their common parent, NovaQuest, could have simply "direct[ed] CoreRx to cease manufacturing for Bionpharma without involving the courts." (Counterclaims ¶ 157.) Bionpharma moved to intervene in the Florida CoreRx lawsuit, allegedly "in order to protect itself against the feigned threat of an injunction against CoreRx's performance of its contractual obligation to supply Bionpharma with Bionpharma's ANDA product." (Counterclaims ¶ 162.) Azurity then settled with CoreRx, wherein CoreRx agreed to stop supplying the generic enalapril oral liquid to Bionpharma. (Counterclaims ¶ 164.)

Based on all the allegations set forth above, Bionpharma claims that Azurity sought to improperly maintain a monopoly in enalapril liquids by punishing generic competition through burdensome and costly litigation. Bionpharma also contends that Azurity brought the First Wave suits solely to obtain the Hatch-Waxman 30-month stay even though Azurity had no expectation of succeeding on the merits. Azurity has moved to dismiss these antitrust counterclaims.

II. LEGAL STANDARD

To survive a motion to dismiss pursuant to Rule 12(b)(6), a complaint must "contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" Ashcroft v. Iqbal, 556 U.S. 662, 678, 129 S.Ct. 1937, 173 L.Ed.2d 868 (2009) (quoting Bell Atlantic Corp. v. Twombly, 550 U.S. 544, 570, 127 S.Ct. 1955, 167 L.Ed.2d 929 (2007)). Conclusory allegations do not suffice. Id. Twombly and Iqbal's plausibility standard requires more than a "sheer possibility that a defendant has acted unlawfully." Id. Plausibility requires "enough facts to raise a reasonable expectation that discovery will reveal evidence of the necessary elements of a claim." Phillips v. County. Of Allegheny, 515 F.3d 224, 234 (3d Cir. 2008).

[1] To determine the sufficiency of a complaint under Twombly and Iqbal, a court must (1) "tak[e] note of the elements a plaintiff must plead to state a claim"; (2) identify the allegations that are not entitled to the assumption of truth because they are no more than conclusions; and (3) "where there are well-pleaded factual allegations, ... assume their veracity and then determine whether they plausibly

give rise to an entitlement for relief." Burtch v. Milberg Factors, Inc., 662 F.3d 212, 221 (3d Cir. 2011). Courts must construe the allegations in a complaint "in the light most favorable to the plaintiff." Id. at 220.

[2] When deciding a motion to dismiss, "courts generally consider only the allegations contained in the complaint, exhibits attached to the complaint and matters of public record." Schmidt v. Skolas, 770 F.3d 241, 249 (3d Cir. 2014).

III. DISCUSSION

Azurity contends that Bionpharma's antitrust claims should be dismissed for six separate reasons, each of which is addressed below.

A. Compulsory Counterclaims

Azurity first argues that Bionpharma's antitrust claims should be barred because they were compulsory counterclaims that Bionpharma should have asserted when the First Wave suits were filed.

[3] A counterclaim is compulsory if it "bears a logical relationship" to the primary claim. Xerox Corp. v. SCM Corp., 576 F.2d 1057, 1059 (3d Cir. 1978). A logical relationship, in turn, depends on whether the two claims "involve many of the same factual issues, or the same factual and legal issues, or where they are offshoots of the same basic controversy between the parties." Id. Under this standard, Azurity argues that the First Wave suits were for patent infringement and that Bionpharma's antitrust claims in the present lawsuit include allegations that bear a logical relationship to the First Wave suits.

"Whether a Sherman Act antitrust claim is a compulsory counterclaim in a patent infringement action is a question of considerable debate." P & M Services, Inc. v. Gubb, No. 07-cv-12816, 2008 WL 4185903, at *3 (E.D. Mich. Sept. 8, 2008). The closest binding precedent on this issue is the Supreme Court's decision in Mercoid Corp. v. Mid-Continent Investment Co., 320 U.S. 661, 64 S.Ct. 268, 88 L.Ed. 376 (1944). There, with little discussion regarding the compulsory counterclaim test, the Supreme Court appeared to assume that an antitrust claim alleging that the patentee had attempted to expand its patent to cover an unpatented component of the invention by suing a user of such a component was not a compulsory counterclaim to the infringement suit. See id. at 671, 64 S.Ct. 268. In a clearer pronouncement, the Ninth Circuit has interpreted Mercoid as holding that a claim of "predatory patent litigation" is not a compulsory counterclaim to a claim of infringement. Hydranautics v. FilmTec Corp., 70 F.3d 533, 536-37 (9th Cir. 1995) ("Mercoid leaves open the possibility of raising antitrust claims ... in a separate and subsequent action.").

The Second Circuit, by contrast, views Mercoid as an "exception" to the compulsory counterclaim rule that has been "subject to serious criticism" and has opined that Mercoid should be "limited to [its] facts." Critical-Vac Filtration Corp. v. Minuteman International, Inc., 233 F.3d 697, 701, 702 n.6 (2d Cir. 2000). However, for claims alleging patent misuse (as opposed to misconduct before the Patent and Trademark Office), the Second Circuit acknowledged that Mercoid is binding and thus permits such claims to be raised in a subsequent litigation. Id. at 704; see also Rohm & Haas Co. v. Brotech Corp., 770 F. Supp. 928, 932 (D. Del. 1991) (recognizing a similar distinction).

The Second and Ninth Circuits also agree that it is relevant that, when antitrust claims are brought as counterclaims in an infringement action, courts often bifurcate the antitrust claims. This common practice weighs against viewing the antitrust claims as compulsory counterclaims:

> If patent infringement claims are frequently bifurcated from antitrust counter-claims and tried separately under Rule 42(b), it would seem that the same underlying logic would apply equally to Rule 13(a). In other words, if judicial economy is promoted by severing two claims and trying them separately, it would seem inappropriate and illogical to regard either claim as a compulsory counter-claim to the other and require consolidation.

Critical-Vac, 233 F.3d at 703 (quoting Teague I. Donahey, Antitrust Counterclaims in Patent Infringement Litigation: Clarifying the Supreme Court's Enigmatic Mercoid Decision, 39 IDEA: J.L. & Tech. 225, 249-50 (1999)); Hydranautics, 70 F.3d at 536.

[4] An additional reason for not treating antitrust counterclaims as compulsory is that they resemble traditional malicious prosecution claims, which are generally not considered compulsory. Hydranautics, 70 F.3d at 536-37; see also T.C.R. Realty, Inc. v. Cox, 472 Pa. 331, 372 A.2d 721, 728 (1977). A malicious prosecution claim, like a sham litigation claim, "arises from the [allegedly wrongful] legal proceeding, not from the same transactions or occurrences from which [that proceeding] arose." T.C.R. Realty, 372 A.2d at 728.

[5] Also instructive is the accrual rule for antitrust damages. "[F]uture damages that might arise from the conduct sued on are unrecoverable if the fact of their accrual is speculative or their amount and nature unprovable." Zenith Radio Corp. v. Hazeltine Research, Inc., 401 U.S. 321, 339, 91 S.Ct. 795, 28 L.Ed.2d 77 (1971). "In these instances, the cause of action for future damages, if they ever occur, will accrue only on the date they are suffered[.]" Id.

[6] At this juncture, it is unnecessary for me to resolve the disagreement between Azurity and Bionpharma over whether Bionpharma's antitrust counterclaims actually accrued when the First Wave suits were filed. The possibility that antitrust claims might not accrue until sometime after Hatch-Waxman infringement litigation plays out suggests that they do not "bear[ ] a logical relationship" to that infringement suit. Xerox Corp., 576 F.2d at 1059. When Bionpharma filed its answer to the First Wave suits, there was no guarantee that the FDA would ever approve Bionpharma's ANDA. It was thus arguably unknown at the time whether the First Wave lawsuits would ever suppress competition, even if they were brought in bad faith. Cf. AstraZeneca AB v. Glenmark Generics, Ltd., No. 14-cv-665, 2014 WL 5366050, at *1 n.1 (D. Del. Oct. 9, 2014) (finding no antitrust claim where generic was unable to enter the market). And, if Azurity had prevailed in the First or Second Wave suits, Bionpharma could not allege it suffered an antitrust injury because Azurity would have lawfully kept Bionpharma off the market. It would not serve "fairness and considerations of convenience and of economy" to require Bionpharma to plead, speculatively, upon being sued in the First Wave, that it would someday have a viable, noninfringing product. Xerox Corp., 576 F.2d at 1059.

Azurity relies on U.S. Philips Corp. v. Sears Roebuck & Co., 55 F.3d 592 (Fed. Cir. 1995), for the proposition that "the place to challenge litigation as sham is in the asserted sham litigation," but Philips involved highly unusual facts that are distinguishable from the case before me. In Philips, the antitrust claimant (Izumi) was a defendant in two simultaneous infringement suits in two different courts. See id. at 593. In the first suit, a codefendant raised antitrust counterclaims, which were tried together with the patent claims at Izumi's insistence. Id. When Izumi attempted to assert similar antitrust counterclaims in the second lawsuit, the court

denied that request but invited Izumi to assert those claims in the first lawsuit. Id. The Federal Circuit affirmed the refusal to let Izumi litigate its antitrust counterclaims in the second lawsuit, reasoning that because Izumi had successfully argued in the first lawsuit that the antitrust and infringement claims must be tried together, it was judicially estopped from splitting those claims in the second lawsuit. Id. at 596-97. In short, Philips dealt with parallel, simultaneous lawsuits and judicial estoppel. That case is thus inapplicable to the situation before me, and, moreover, the Federal Circuit expressly disavowed holding that a sham litigation claim was " 'compulsory' in the technical definition of this term." Id. at 595.

Given all of the above, I find the Ninth's Circuit's reasoning in Hydranautics persuasive, and conclude that in viewing the present allegations as true, Bionpharma's antitrust claims were not compulsory counterclaims in the First Wave suits.

B. Antitrust Injury

[7] Azurity next argues that Bionpharma cannot show antitrust injury because Azurity's law-suits failed to keep Bionpharma's generic product off the market. In Azurity's view, even if those lawsuits harmed Bionpharma by forcing Bionpharma to incur litigation costs, the antitrust laws only protect competition, not individual competitors. See Atlantic Richfield Co. v. USA Petroleum Co., 495 U.S. 328, 344, 110 S.Ct. 1884, 109 L.Ed.2d 333 (1990). Therefore, Azurity reasons, Bionpharma cannot show that there was harm to competition in the enalapril liquid market, and Bionpharma's antitrust claims should be dismissed.

The Federal Circuit addressed this situation in TransWeb, LLC v. 3M Innovative Properties Co., 812 F.3d 1295 (Fed. Cir. 2016). In that patent infringement lawsuit, the alleged infringer brought an antitrust counterclaim alleging that the patent was fraudulently obtained (a so-called "Walker Process claim"). Id. at 1306. The infringement suit was unsuccessful but the antitrust claim succeeded, with the district court awarding attorneys' fees as antitrust damages. Id. In affirming the damages award, the Federal Circuit held that those attorneys' fees constituted "an antitrust injury" even though "[the patentee] fail[ed] to prevail in [its] lawsuit" and thus failed to keep the accused product off the market. Id. at 1308-12. TransWeb therefore directly addressed and rejected the argument Azurity makes here.

Azurity relies on Otsuka Pharmaceutical Co. v. Torrent Pharmaceuticals Limited, 187 F. Supp. 3d 483 (D.N.J. 2016), which distinguished TransWeb on the ground that "TransWeb, LLC addressed itself to the issue of recoverable antitrust damages" as opposed to whether there had been an antitrust injury at all. Otsuka, 187 F. Supp. 3d at 486 n.6 (emphasis in original). Aside from the fact that I am not bound by Otsuka, TransWeb did in fact hold that attorneys' fees were an "an antitrust injury." 812 F.3d at 1299.

C. Causation

[8] Azurity also challenges Bionpharma's allegation that the First Wave suits delayed the entry of Bionpharma's generic enalapril liquid to market. Specifically, Bionpharma alleges that the automatic 30-month stay that applies in Hatch-Waxman litigation, and which remained in effect from the First Wave suits until April 30, 2021, delayed Bionpharma's ability to market its enalapril liquid until August 17, 2021. (Counterclaims ¶¶ 193, 201.) Azurity responds that because there was a three-and-a-half-month gap between the expiration of the 30-month stay and Bionpharma's market entry, it cannot be inferred

that Bionpharma could have entered the market sooner but for the stay.

Bionpharma's allegation that the 30-month stay delayed its entry must be accepted as true at the pleadings stage. Iqbal, 556 U.S. at 678, 129 S.Ct. 1937. It is also plausible under the Twombly standard that a legal prohibition on the FDA granting final approval would delay launch of the product. Azurity's counterargument implicates a factual dispute that is not appropriate for resolution at this stage of the litigation.

Azurity also asserts that its lawsuits could not have harmed competition because it had an alternative way to keep Bionpharma's generic enalapril liquid off the market. Namely, Azurity's parent NovaQuest could have simply asked Azurity's corporate sister CoreRx to stop manufacturing the product for Bionpharma. (See Azurity's Brief at 18 ("[Bionpharma's] but-for world is the same as the real world[.]").) This is an unusual argument that appears to suggest that because Azurity could have suppressed competition some other way, it should not be held liable for the method it in fact chose. Unsurprisingly, Azurity cites no authority for this argument.

D. Noerr-Pennington Part 1: Objective Baselessness

[9] Azurity's next argument for dismissal is that its lawsuits were protected under the Noerr-Pennington doctrine. "The filing of a lawsuit carries significant constitutional protections, implicating the First Amendment right to petition the government for redress of grievances, and the right of access to courts." Hoeber v. Local 30, United Slate, Tile & Composition Roofers, Damp & Waterproof Workers Ass'n, 939 F.2d 118, 126 (3d Cir. 1991). Under the Noerr-Pennington doc trine, such lawsuits "are generally immune from antitrust liability" unless certain exceptions are met. FTC v. AbbVie Inc., 976 F.3d 327, 359-60 (3d Cir. 2020). To overcome Noerr-Pennington immunity, an antitrust plaintiff must show that: (1) "the lawsuit [was] objectively baseless in the sense that no reasonable litigant could [have] realistically expect[ed] success on the merits"; and (2) "the baseless lawsuit conceals an attempt to interfere directly with the business relationships of a competitor through the use of the governmental process—as opposed to the outcome of that process—as an anticompetitive weapon." Id. at 360.

[10] Azurity contends that certain events that occurred in the First Wave show that those lawsuits were not objectively baseless. According to Azurity, those events are: (1) Judge Stark denying leave to file a motion for judgment on the pleadings; (2) Judge Stark hearing five days of testimony and authoring a 70-page opinion; (3) Bionpharma not seeking leave to file a motion for summary judgment; and (4) the Federal Circuit granting oral argument in the appeal from the First Wave suits. Whether these events show that Azurity's lawsuits were not objectively baseless is a factual question that cannot be resolved on a motion to dismiss.

Azurity also takes issue with the substance of Bionpharma's reasons for calling Azurity's seven lawsuits objectively baseless. Bionpharma alleges that Azurity's lawsuits were objectively baseless for numerous reasons, involving issues of infringement, validity, licensing, and jurisdiction. At this stage of the litigation, it is not necessary to analyze all of Bionpharma's allegations that Azurity's lawsuits were objectively baseless. Instead, because two of these allegations involve all seven lawsuits, for purposes of a motion to dismiss analysis it is sufficient to examine two of these allegations, which claim: (1) that the First and Second Wave suits were objectively baseless because Bionpharma's

ANDA does not contain an equivalent to a citrate buffer; and (2) that the Third Wave and CoreRx suits were objectively baseless because the Third Wave patents' specification does not describe liquids without buffers.

Before analyzing the substance of these allegations, it is necessary to make two preliminary points. First, while Judge Stark entered judgment in Bionpharma's favor as to some of Bionpharma's allegations, the mere fact that Azurity lost on these grounds does not mean that its position was objectively baseless from the start. Professional Real Estate Investors, Inc. v. Columbia Pictures Industries, Inc. (PRE), 508 U.S. 49, 60 n.5, 113 S.Ct. 1920, 123 L.Ed.2d 611 (1993). Indeed, Azurity contends that the positions it took in the First Wave were colorable even if Judge Stark did not ultimately agree with them.

Second, although it is sometimes possible to decide whether a lawsuit was objectively baseless "as a matter of law," PRE, 508 U.S. at 63, 113 S.Ct. 1920, not all of the facts underlying Bionpharma's antitrust allegations are undisputed. For example, it is a factual question whether Azurity had a basis to believe that certain ingredients in Bionpharma's ANDA could act as a buffer. In addition, while legal issues underlying Bionpharma's allegations might be resolvable at the pleadings stage, Azurity's motion contains only a cursory analysis of those issues, which is inadequate for me to conclude, at this juncture, that Bionpharma's allegations necessarily fail as a matter of law.

With those points in mind, I consider whether two of Bionpharma's allegations plausibly give rise to an inference that the First Wave, Second Wave, Third Wave, and CoreRx suits were objectively baseless.

1. Lack of Claimed Buffer in Bionpharma's ANDA

The patents asserted in the First Wave suits claimed buffers made from citric acid and sodium citrate. As to some of those claims, the language was amended during the prosecution history to add sodium citrate. Bionpharma argued in the First Wave suits that the amendment triggered amendment-based prosecution history estoppel—such that Azurity could not claim solutions lacking sodium citrate. Bionpharma alleges that Azurity's position that it could overcome this defense was objectively baseless, such that Noerr-Pennington immunity does not apply.

In its present motion, Azurity asserts it "believed the amendment was made for clarification purposes and was not a narrowing amendment," but Azurity does not explain why the pleadings compel the conclusion that this belief was objectively colorable. It therefore remains a factual dispute whether Azurity had an objective basis for alleging that Bionpharma's ANDA infringed the First Wave patents, and I thus decline to dismiss Bionpharma's counterclaims as to this ground.

2. Lack of Written Description Supporting Liquids Without Buffers

The Third Wave patents differ from the First Wave patents in that the Third Wave patents claim formulations that lack buffers. Bionpharma alleges that the specification does not support formulations without buffers and that, therefore, the Third Wave patents are invalid for lack of written description. And Bionpharma asserts that it was objectively baseless for Azurity to claim that it could overcome this invalidity defense.

Azurity responds only that there is a presumption that an issued patent is valid and does not address the substance of Bionpharma's argument. I therefore cannot conclude, at this stage, that Azurity

necessarily had an objective basis to assert the Third Wave patents against Bionpharma's ANDA.

For these reasons, Bionpharma has plausibly alleged the first prong of the exception to Noerr-Pennington immunity by alleging that Azurity's seven lawsuits were objectively baseless. Whether these lawsuits were in fact objectively baseless remains an issue for factual development.

E. Noerr-Pennington Part 2: Subjective Motivation

[11, 12] Azurity next contends that Bionpharma has not adequately pled the subjective component necessary to overcome Noerr-Pennington immunity "Under the subjective motivation prong, a plaintiff must show the defendant brought baseless claims in an attempt to thwart competition (i.e., in bad faith)." FTC v. AbbVie, 976 F.3d at 360 (quotation marks omitted).

Bionpharma alleges several facts that it argues raise a plausible inference that Azurity intended to thwart competition:

First, Bionpharma alleges that Azurity turned down an opportunity to view Bionpharma's ANDA before filing the First Wave suits, suggesting that Azurity was disinterested in learning whether those suits were viable. See FTC v. AbbVie, 976 F.3d at 360 (a relevant factor is "whether the defendant was indifferent to the outcome on the merits of the suit" (alterations and quotation marks omitted)).

Second, Bionpharma points to the number of lawsuits—seven across three courts—and reasons that Azurity's nine patents on enalapril liquids enabled it to file new lawsuits as patents were issued. Bionpharma notes that the FDA has raised concerns that "the practice of filing 'continuation' patent applications ... can allow companies to create 'patent thickets' by obtaining multiple patents on different aspects of the same product within a patent application," a practice which "increases litigation burdens and potentially delays the approval of generics...." See September 10, 2021 Letter from Acting Commissioner Woodcock to the USPTO at 3, https://www.fda.gov/media/152086/download.

Third, Bionpharma alleges that because Azurity's lawsuits were baseless, an experienced litigant like Azurity would only bring them for a reason other than eventual success on the merits. See FTC v. AbbVie, 976 F.3d at 369 ("Evidence that a defendant knew its claims were meritless may help a plaintiff to show a defendant was indifferent to the outcome on the merits of the suit and decided to sue primarily for the benefit of collateral injuries inflicted through the use of legal process." (alterations and quotation marks omitted)).

Azurity responds to these allegations primarily by identifying contrary facts that it claims show a proper motivation for filing suit, such as that it spent time and resources litigating an appeal. Azurity also notes that the Hatch-Waxman Act gives a patentholder a short window to decide whether to file a lawsuit and states that it had a legitimate, unspecified reason to turn down Bionpharma's offer of confidential access. Whether these countervailing reasons will ultimately demonstrate that Azurity's lawsuits were brought in good faith is a factual question that cannot be resolved at this stage.

Azurity also objects to consideration of the number of lawsuits it filed, citing authority that an accusation of "serial petitioning" is inapplicable to Hatch-Waxman lawsuits because Congressional policy favors prompt resolution of property rights. See In re Wellbutrin XL Antitrust Litigation, 868 F.3d 132, 157-58 (3d Cir. 2017). But Azurity's cited authority is addressed to the situation where a brand manufacturer sues multiple different generic competitors, as Hatch-Waxman requires it to. See id.; Kaiser Foundation Health Plan, Inc. v.

Abbott Labs., Inc., 552 F.3d 1033, 1047 (9th Cir. 2009) (finding repeated Hatch-Waxman lawsuits were not sham litigations because "the volume of [the patentee's] suits was dependent on the number of generic companies attempting to enter the . . . marketplace, a matter over which [the patentee] had no control"). Here, Azurity filed seven lawsuits over the same generic product and has not pointed to anything in the Hatch-Waxman Act that endorses such a practice.

For these reasons, Bionpharma has plausibly alleged that Azurity filed its seven lawsuits to interfere with competition in enalapril liquids through means other than eventual success on the merits. Whether that was Azurity's actual motivation remains an issue for factual development.

F. Intent to Monopolize

Lastly, and somewhat cursorily, Azurity asserts that Bionpharma "fails to sufficiently allege a specific intent to monopolize." Azurity also states that Bionpharma's "allegations amount to, at most, an intent to exclude infringing products, which is insufficient."

Largely for the reasons set out in the previous section, Bionpharma's allegations raise a plausible inference that Azurity "ha[d] the specific intent to . . . monopolize the [enalapril liquid] Market." (Counterclaims ¶ 257.) Whether Bionpharma's product was infringing such that Azurity could legitimately exclude it is a subject of ongoing dispute that cannot be resolved at this time.

IV. CONCLUSION

For the reasons set out above, Azurity's motion to dismiss will be denied.

An appropriate order follows.

Eric SUBER et al., on their own behalf and on behalf of all others similarly situated

v.

LIBERTY MUTUAL INSURANCE GROUP et al.

CIVIL ACTION NO. 21-4750

United States District Court, E.D. Pennsylvania.

Signed March 30, 2022

Background: Insured motorist brought putative class action against insurer, insurer's parent company, holding company which owned parent company, and sister company of insurer, alleging breach of contract and seeking declaratory judgment arising from denial of claims subject to an exclusion related to racing events. Defendants moved to dismiss, and insured moved to strike portions of insurer's answer.

Holdings: The District Court, McHugh, J., held that:

(1) fact that coverage-denial letter was signed by a claims resolution specialist who identified himself as an agent for both insurer and for sister company was not a contact of sister company with forum state that was sufficiently connected to claims at issue, as could allow exercise of specific jurisdiction over sister company;

(2) fact that footer of coverage-denial letter sent to insured included a hyperlink to lines of insurance issued by sister company was not a contact of sister company with forum state that could support exercise of specific jurisdiction over sister company;

(3) insurer's use of brand and logo for holding company was not a contact of holding company with forum state that was connected to claims at issue, as